Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-17-0888]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Within 30 days of this notice, direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806.

Proposed Project

Factors Influencing the Transmission of Influenza (OMB Control Number 0920-0888; Expired 6-30-2017) – Reinstatement with change – National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC)

Background and Brief Description

The National Institute for Occupational Safety and Health (NIOSH) is authorized to conduct research to advance the health and safety of workers under Section 20(a)(1) of the 1970 Occupational Safety and Health Act. Influenza continues to be a major public health concern because of the substantial health burden from seasonal influenza and the potential for a severe pandemic. Although influenza is known to be transmitted by infectious secretions, these secretions can be transferred from person to person in many different ways, and the relative importance of the different pathways is not known. The likelihood of the transmission of influenza virus by small infectious airborne particles produced during coughing and breathing is particularly unclear. The question of airborne transmission is especially important in healthcare facilities, where influenza patients tend to congregate during influenza season, because it directly impacts the infection control and personal protective measures that should be taken by healthcare workers.

Work under the previous approval showed that patients infected with influenza virus produce airborne particles containing viable airborne influenza virus during both breathing and coughing, but that breathing may generate more airborne infectious material than coughing over time. However, this work was hampered because the amounts of influenza virus in almost

all of the aerosol samples were below the limit of quantification. Thus, CDC made the following changes to the project:

1) CDC will modify the cough and exhalation-aerosol collection system to collect aerosol particles continuously for 40 minutes, rather than collecting particles from discrete coughs and exhalations as in the previous study. This will increase the amount of influenza virus that is collected.

2) Researchers will collect a blood sample from each participant to allow testing for blood markers of influenza infection and a comparison of the levels of these markers to the amount of expelled influenza in aerosol particles.

3) Researchers increased the time required for participation from 63 minutes to 95 minutes to allow for a longer aerosol collection period and for the blood collection.

4) Researchers will recruit and test an equal number of control subjects without symptoms of respiratory illness in addition to subjects with influenza-like illness. This will allow the determination of the differences in blood biomarker levels between healthy and infected subjects.

5) Because of the longer participation time and because blood collection has been found to be a strong disincentive for participation, the token of appreciation for participating in the study has been increased from $25 to $40.

The purpose of the proposed study is to gain a better understanding of the production of infectious aerosols by patients with influenza, and to compare this to the levels of biomarkers of influenza infection in the blood of these patients. To do this, researchers will collect airborne particles produced by volunteer subjects with influenza to test for influenza virus. Researchers will also measure the levels of influenza infection-associated biomarkers in blood samples from these subjects.

A test coordinator will recruit volunteer adult participants by using a poster and flyers describing the study. Researchers will verbally screen interested potential participants to verify that they have influenza-like symptoms and that they do not have any medical conditions that would preclude their participation. Researchers will also recruit a matching number of healthy control participants.

Researchers will ask qualified participants who agree to participate in the study to read and sign an informed consent form, and then to complete a short health questionnaire. After completing the forms, researchers will measure the participant's oral temperature and collect two nasopharyngeal mucus samples and five ml of blood. The researchers will then ask the participants to don elastomeric masks, and breathe and cough normally for 40 minutes into an aerosol particle collection

system. The total time from initial verbal screening to completion will be about 95 minutes.

The study will require 90 volunteer test subjects each year for 3 years, totaling 270 test participants. There are no costs to respondents other than their time. The total number of annual burden hours are 148.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
Potential participant	Initial verbal screening	180	1	3/60
Qualified participant	Informed consent form	90	1	15/60
Qualified participant	Health questionnaire	90	1	5/60
Qualified participant	Medical testing	90	1	72/60

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